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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
07/542,149	06/22/1990	WITOLD CIEPLAK JR.		1598

27123

7590

10/16/2009

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EXAMINER

KAM, CHIH MIN

ART UNIT

PAPER NUMBER

1656

NOTIFICATION DATE

DELIVERY MODE

10/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

07/542,149

Applicant(s)

CIEPLAK, WITOLD

Examiner

CHIH-MIN KAM

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 June 1990 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

Status of the Claims

1. Claims 11, 13 and 15-16 are pending.

An order to terminate the interference by the Board of Patent Appeals and Interferences was mailed on October 22, 2003. Therefore, claims 11, 13 and 15-16 are examined.

Priority

2. The instant application is a continuation of U.S. Application Serial No. 07/311,612, filed 2/15/1989, now abandoned, which is a CIP of 06/843,727, filed 3/25/1986, now U.S. Patent 4,883,761. Since the application 06/843,727 does not disclose a DNA molecule encoding a mutant of the S1 subunit of *Bordetella pertussis* toxin, thus the priority date for instant claims 11, 13 and 15-16 is the filing date of 07/311,612, February 15, 1989.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 11, 13 and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Burnette, III (U. S. Patent 5,773,600, effective filing date 9/4/1987).

Burnette teaches a recombinant DNA molecule comprising a nucleotide sequence encoding a mutant S1 subunit of Bordetella exotoxin which differs from the native sequence of the S1 subunit by comprising a residue other than arginine (e.g., lysine) substituted for arginine at the ninth position from the mature N-terminus, wherein a holotoxin of Bordetella exotoxin comprising the mutant S1 subunit elicits Bordetella exotoxin-neutralizing antibodies and lacks enzymatic activity associated with Bordetella exotoxin reactogenicity (column 7, line 56-column 16; Tables I and II; claims 11, 13 and 15-16).

4. Claims 11, 13 and 15-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein *et al.* (U. S. Patent 5,358,868, effective filing date 11/23/1988).

Klein *et al.* teaches a method for the production of immunoprotective genetically detoxified mutant of pertussis holotoxin by identifying specific functional sites (e.g., Arg9) of pertussis toxin and production of recombinant holotoxins by site-directed mutagenesis of the holotoxin gene (column 5, line 43-column 9; claims 11 and 15), where the resulting toxin mutants (e.g., Lys9 and His9) are detoxified, retain an immunodominant S1 epitope, are immunogenic and are protective against the disease pertussis (column 22, line 41-column 26; Table 1a, 1b and 2; claims 13 and 16).

Conclusion

5. No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chih-Min Kam/

Primary Examiner, Art Unit 1656

/Cecilia Tsang/

Supervisory Patent Examiner, Art Unit
1654

CMK

September 30, 2009